107TH CONGRESS
2D SESSION

S. 2677

To improve consumer access to prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 25, 2002

Mr. ROCKEFELLER introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To improve consumer access to prescription drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Consumer Access to Prescription Drugs Improvement Act of 2002''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) prescription drugs are a crucial part of modern medicine, serving as complements to medical procedures, substitutes for surgery and other medical procedures, and new forms of treatment;

(2) a lack of access to prescription drugs can not only cause discomfort, but can be life-threatening to a patient;

(3)(A) by all accounts, double-digit prescription drug price increases are forecast annually for the next 3 to 5 years; and

(B) such increases would result in prescription drug costs that would be prohibitive for many Americans;

(4) the Congressional Budget Office estimates that—

(A) the use of generic prescription drugs for brand-name prescription drugs could save purchasers of prescription drugs between $8,000,000,000 and $10,000,000,000 each year; and

(B) generic prescription drugs cost between 25 percent and 60 percent less than brand-name prescription drugs, resulting in an estimated average saving of $15 to $30 on each prescription;

(5) expanding access to generic prescription drugs can help consumers, especially seniors and the uninsured, have access to more affordable prescription drugs;

(6) policymakers should be better informed about issues relating to prescription drugs, particu-

larly issues concerning barriers to patient access to prescription drugs;

(7) health care purchasers should be more aware of safe, cost-effective alternatives to brand-name prescription drugs; and

(8) prescription drug coverage provided under existing programs should be expanded to better reflect modern technology and provide drugs to the people who rely on them most, yet who increasingly find themselves uninsured or with coverage that is becoming more expensive and less meaningful.

(b) PURPOSES.—The purposes of this Act are—

(1) to better educate policymakers, purchasers, and the public about safe and cost-effective generic alternatives, barriers to market entry, and upcoming issues in the pharmaceutical industry;

(2) to increase consumer access to prescription drugs by—

(A) decreasing price through increased competition; and

(B) expanding coverage under the medicare and medicaid programs.

TITLE I—EXPANSION OF ACCESS THROUGH EDUCATION AND INFORMATION

SEC. 101. PHARMACEUTICAL ADVISORY COMMITTEE.

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by inserting after section 1805 the following:

''PHARMACEUTICAL ADVISORY COMMITTEE

''SEC. 1805A. (a) ESTABLISHMENT.—There is established, as part of the Medicare Payment Advisory Commission established under section 1805, a committee to be known as the 'Pharmaceutical Advisory Committee' (referred to in this section as the 'Committee').

''(b) MEMBERSHIP.—

''(1) COMPOSITION.—The Committee shall be composed of 11 members appointed by the Comptroller General of the United States.

''(2) QUALIFICATIONS.—

''(A) IN GENERAL.—The Committee members shall be selected from among—

''(i) individuals with expertise in and knowledge of the pharmaceutical industry (brand name and generic), including expertise in and knowledge of pharmaceutical—

''(I) development;

''(II) pricing;

''(III) distribution;

''(IV) marketing;

''(V) reimbursement; and

''(VI) patent law; and

''(ii) providers of health and related services;

''(B) REPRESENTATION.—The members of the Committee shall include—

''(i) physicians and other health professionals;

''(ii) employers;

''(iii) third-party payers;

''(iv) representatives of consumers;

''(v) individuals having—

''(I) skill in the conduct and interpretation of pharmaceutical and health economics research; and

''(II) expertise in outcomes, effectiveness research, and technology assessment; and

''(vi) patent attorneys.

''(C) CONFLICTS OF INTEREST.—The members of the Committee shall not include any individual who, within the 5-year period

preceding the date of appointment to the Committee, has been an officer or employee of a drug manufacturer or has been employed as a consultant to a drug manufacturer.

''(D) REPRESENTATION.—The members of the Committee shall be broadly representative of various professions, geographic regions, and urban and rural areas.

''(E) LIMITATION.—Not more than ½ of the members appointed under this subsection may be directly involved in the provision, management, or delivery of items and services covered under this title.

''(F) PUBLIC DISCLOSURE.—As soon as practicable after the date of enactment of this Act, the Comptroller General of the United States shall establish rules for the public disclosure of financial and other potential conflicts of interest by members of the Committee.

''(3) TERMS; VACANCIES.—

''(A) TERMS.—

''(i) IN GENERAL.—Except as provided in clause (ii), a member of the Committee shall be appointed for a term of 3 years.

"(ii) INITIAL TERMS.—Of the members first appointed to the Committee under this subsection—

"(I) 4 shall be appointed for a term of 1 year; and

"(II) 4 shall be appointed for a term of 2 years.

"(iii) CARRYOVER.—After the term of a member of the Committee has expired, the member may continue to serve until a successor is appointed.

"(B) VACANCIES.—

"(i) IN GENERAL.—A vacancy on the Committee—

"(I) shall not affect the powers of the Committee; and

"(II) shall be filled in the same manner as the original appointment was made.

"(ii) FILLING OF UNEXPIRED TERM.—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

"(4) MEETINGS.—The Committee shall meet at the call of the chairperson.

''(5) CHAIRPERSON; VICE CHAIRPERSON.—The Comptroller General shall appoint 1 of the members as chairperson and 1 of the members as vice chairperson.

''(c) DUTIES.—

''(1) IN GENERAL.—The Committee shall—

''(A) review payment policies for drugs under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq.); and

''(B) make recommendations to Congress with respect to the payment policies.

''(2) INCLUSIONS.—The matters to be studied by the Committee under paragraph (1) include—

''(A) the effects of direct-to-consumer advertising, drug detailing, and sampling;

''(B) the level of use of generic drugs as safe and cost-effective alternatives to brand name drugs;

''(C) the barriers to approval of generic drugs, including consideration of all of the matters described in paragraph (3);

''(D) the adequacy of drug price metrics, including the average wholesale price and the average manufacturers price;

"(E) the effectiveness of various education methods on changing clinical behavior;

"(F) the effectiveness of common drug management tools, including drug use review and use of formularies;

"(G) the perception of patients, physicians, nurses, and pharmacists of generic prescription drugs as safe and effective substitutes for brand-name prescription drugs;

"(H) the costs of research and development and the costs of clinical trials associated with producing a drug;

"(I) the relationship between pharmacy benefit managers and prescription drug manufacturers;

"(J) best practices to increase medical safety and reduce medical errors; and

"(K) polypharmacy and underutilization.

"(3) BARRIERS TO APPROVAL.—The matters for consideration referred to in paragraph (2)(C) include—

"(A) the appropriate balance between rewarding scientific innovation and providing affordable access to health care;

''(B) features of the communication process and grievance procedure of the Committee that provide opportunities for tactics that unduly delay generic market entry;

''(C) the use of the citizen's petition process to delay generic market entry;

''(D) the use of changes to a drug product (including a labeling change) timed to delay generic approval; and

''(E) the impact of granting patents on diagnostic methods such as patents on genes and genetic testing systems on access to affordable health care.

''(4) REPORT.—Not later than January 1 of each year, the Committee shall submit to Congress a report on—

''(A) the results of the reviews and recommendations;

''(B) issues affecting drug prices, including use of and access to generic drugs; and

''(C) the effect of drug prices on spending by government-sponsored health care programs and health care spending in general.

''(d) POWERS.—

''(1) INFORMATION FROM FEDERAL AGENCIES.—

''(A) IN GENERAL.—The Committee may secure directly from a Federal department or agency such information as the Committee considers necessary to carry out this section.

''(B) PROVISION OF INFORMATION.—On request of the Chairperson of the Committee, the head of the Federal department or agency shall provide the information to the Committee.

''(2) DATA COLLECTION.—To carry out the duties of the Committee under subsection (c), the Committee shall—

''(A) collect and assess published and unpublished information that is available on the date of enactment of this Act;

''(B) if information available under subparagraph (A) is inadequate, carry out, or award grants or contracts for, original research and experimentation; and

''(C) adopt procedures to allow members of the public to submit information to the Committee for inclusion in the reports and recommendations of the Committee.

''(3) ADDITIONAL POWERS.—The Committee may—

''(A) seek assistance and support from appropriate Federal departments and agencies;

''(B) enter into any contracts or agreements as are necessary to carry out the duties of the Committee, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5);

''(C) make advance, progress, and other payments that relate to the duties of the Committee;

''(D) provide transportation and subsistence for persons serving without compensation; and

''(E) promulgate regulations for the internal organization and operation of the Committee.

''(e) COMMITTEE PERSONNEL MATTERS.—

''(1) COMPENSATION OF MEMBERS.—

''(A) IN GENERAL.—A member of the Committee shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including

travel time) during which the member is engaged in the performance of the duties of the Board.

''(B) TRAVEL EXPENSES.—A member of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an agency under subchapter I of chapter 57 of title 5, United States Code, while away from the home or regular place of business of the member in the performance of the duties of the Board.

''(2) STAFF.—

''(A) IN GENERAL.—The Committee may, without regard to the civil service laws (including regulations), appoint and terminate an executive director and such other additional personnel as are necessary to enable the Committee to perform the duties of the Committee.

''(B) COMPENSATION.—The Chairperson of the Committee may fix the compensation of the executive director and other personnel without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, relating to classification of positions and General Schedule pay rates.

''(C) EMPLOYEES OF THE FEDERAL GOVERNMENT.—For the purposes of compensation, benefits, rights, and privileges, the staff of the Committee shall be considered employees of the Federal Government.

''(f) REQUEST FOR APPROPRIATIONS.—

''(1) IN GENERAL.—The Committee shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations.

''(2) SEPARATE AMOUNTS.—Notwithstanding paragraph (1), amounts appropriated for the Committee shall be separate from amounts appropriated for the Comptroller General.''.

SEC. 102. GUIDANCE FOR PAYER AND MEDICAL COMMUNITIES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance for the payer community and the medical community on—

(1) how consumers, physicians, nurses, and pharmacists should be educated on generic drugs; and

(2) the need to potentially educate pharmacy technicians, nurse practitioners, and physician assistants on generic drugs.

(b) MATTERS TO BE ADDRESSED.—The guidance shall include such items as—

(1) a recommendation for allotment of a portion of yearly continuing education hours to the subject of generic drugs similar to recommendations for continuing education already in place for pharmacists in some States on pharmacy law and AIDS;

(2) a recommendation to all medical education governing bodies regarding course curricula concerning generic drugs to include in the course work of medical professionals;

(3) a recommendation on how the Food and Drug Administration could notify physicians and pharmacists when a brand name drug becomes available as a generic drug and what information could be included in the notification;

(4) the establishment of a speaker's bureau available to groups by geographic region to speak and provide technical assistance on issues relating to generic drugs, to be available to pharmacists, consumer groups, physicians, nurses, and local media; and

(5) the proposition of a survey on perception and awareness of generic drugs at the beginning and

end of an educational campaign to test the effectiveness of the campaign on different audiences.

(c) PUBLIC EDUCATION.—The Secretary shall provide for the education of the public on the availability and benefits of generic drugs.

(d) NOTIFICATION OF NEW GENERIC PRESCRIPTION DRUG APPROVALS.—As soon as practicable after a new generic prescription drug is approved, the Secretary shall—

(1) notify physicians, pharmacists, and other health care providers of the approval; and

(2) inform health care providers of the brand-name prescription drug for which the generic prescription drug is a substitute.

SEC. 103. STUDY OF PROCEDURES AND SCIENTIFIC STANDARDS FOR EVALUATING GENERIC BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—The Institute of Medicine shall conduct a study to evaluate—

(1) the feasibility of producing generic versions of biological products; and

(2) the relevance of the source materials and the manufacturing process to the production of the generic versions.

(b) ESTABLISHMENT OF PROCESS.—

(1) IN GENERAL.—If, as a result of the study under subsection (a), the Institute of Medicine finds that it would be feasible to produce generic versions of biological products, not later than 3 years after the date of the completion of the study, the Secretary, shall prescribe procedures and conditions under which biological products intended for human use may be approved under an abbreviated application or license.

(2) APPLICATION.—An abbreviated application or license shall, at a minimum, contain—

(A) information showing that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new biological product have been previously approved for a drug subject to regulation under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (referred to in this subsection as a ''listed drug'');

(B) information to show that the new biological product has chemical and biological characteristics comparable to the characteristics of the listed drug; and

(C) information showing that the new biological product has a safety and efficacy profile comparable to that of the listed drug.

(3) PRODUCT STANDARDS.—The Secretary, on the initiative of the Secretary or on petition, may by regulation promulgate drug product standards, procedures, and conditions to determine insignificant changes in a biological product that do not affect the scientific and medical soundness of product approval and interchangeability.

SEC. 104. INSTITUTE OF MEDICINE STUDY.

(a) IN GENERAL.—The Institute of Medicine shall convene a committee to conduct a study to determine—

(1) whether information regarding the relative efficacy and effectiveness of drugs (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) and biological products (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))) is available to the public for independent and external review;

(2) whether the benefits of drugs and biological products, and particularly the relative benefits of similar drugs and biological products, are understood by physicians and patients; and

(3) whether prescribing and use patterns are unduly or inappropriately influenced by marketing to physicians and direct advertising to patients.

(b) RECOMMENDATIONS.—If problems are identified by the study conducted under subsection (a), the committee shall make recommendations to the Commissioner of Food and Drugs for improvement, including recommendations regarding—

(1) ways to better review the relative efficacy and effectiveness of drugs approved for use by the Food and Drug Administration;

(2) the appropriate governmental or nongovernmental body to conduct the review described under paragraph (1); and

(3) ways to improve communication and dissemination of the information reviewed in paragraph (1).

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

TITLE II—EXPANSION OF ACCESS THROUGH INCREASED COMPETITION

SEC. 201. DRUG REIMBURSEMENT FUND.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 501 et seq.) is amended by adding at the end the following:

"SEC. 524. DRUG REIMBURSEMENT FUND.

''(a) DEFINITIONS.—In this section:

''(1) DRUG PATENT.—The term 'drug patent' means a patent described in section 505(b)(1).

''(2) FUND.—The term 'Fund' means the Drug Reimbursement Fund established under subsection (b).

''(b) ESTABLISHMENT.—There is established in the Treasury of the United States a separate fund to be known as the 'Drug Reimbursement Fund'.

''(c) COMPTROLLER.—The Secretary shall appoint a comptroller to administer the Fund.

''(d) REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall promulgate regulations for the operation of the Fund, including the method of payments from the Fund and designation of beneficiaries of the Fund.

''(2) ADMINISTRATIVE DETERMINATIONS.—The regulations under paragraph (1) may permit the administrative determination of the claims of health insurers, State and Federal Government programs, and third-party payers or other parties that are disadvantaged by the conduct of drug manufacturers that seek to bring spurious civil actions for infringement of drug patents in order to block the production and marketing of lower-cost drug alternatives.

''(e) CONTRIBUTIONS TO THE FUND.—

''(1) IN GENERAL.—In any civil action under section 505 or 512 or in a civil action for infringement of a drug patent (as defined in section 524(a)) under chapters 28 and 29 of title 35, United States Code—

''(A) if the Court determines that the drug patent is invalid or that the drug patent is not otherwise infringed, but that the plaintiff obtained an injunction against the defendant for the production or marketing of the drug to which the drug patent relates, the Court shall order the plaintiff to pay to the Fund the amount that is equal to—

''(i) the amount that is equal to the amount of net revenues generated by the

plaintiff from the production or marketing of the drug during the period in which the injunction was in effect, plus an additional period of 12 months; minus

''(ii) the amount of any special damages paid by the plaintiff under section 524(m); or

''(B) if the defendant enters into a settlement agreement or any other arrangement under which the defendant agrees to withdraw an application under section 505 or 512, the Court shall order the defendant to pay to the Fund the amount that is equal to 50 percent of the amount (including the value of any form of property) that the defendant receives from the plaintiff under the arrangement.

''(2) COLLECTION.—The United States may seek to enforce collection of a contribution required to be made to the Fund by bringing a civil action in United States district court.''.

SEC. 202. PATENT CERTIFICATION.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)—

(A) by striking ''(B) The approval'' and inserting the following:

''(B) EFFECTIVE DATE OF APPROVAL.—Except as provided in subparagraph (C), the approval''; and

(B) by striking clause (iii) and inserting the following:

''(iii) CERTIFICATION THAT PATENT IS INVALID OR WILL NOT OTHERWISE BE INFRINGED.—

''(I) NO CIVIL ACTION FOR PATENT INFRINGEMENT OR DECLARATORY JUDGMENT, OR NO MOTION FOR PRELIMINARY INJUNCTION.—Except as provided in subclause (II), if—

''(aa) the applicant made a certification described in paragraph (2)(A)(vii)(IV);

''(bb) none of the conditions for denial of approval stated in paragraph (4) applies;

''(cc)(AA) no civil action for infringement of a patent that is the subject of the certification is brought before the expiration of

the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; or

"(BB) a civil action is brought as described in subitem (AA), but no motion for preliminary injunction is filed within 90 days of commencement of the civil action; and

"(dd) the applicant does not bring a civil action for declaratory judgment of invalidity or other noninfringement of the patent before the expiration of the 60-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received;

the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received.

"(II) CIVIL ACTION FOR PATENT INFRINGEMENT OR DECLARATORY JUDGMENT.—If—

"(aa)(AA) a civil action for infringement of a patent that is the subject of the certification is brought before the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; or

"(BB) the applicant brings a civil action for declaratory judgment of invalidity or other noninfringement of the patent before the expiration of the 60-day period beginning on the date on which the notice under paragraph (2)(B)(ii) was received;

"(bb) the holder of the approved application or the owner of the patent seeks a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture and sale of the drug; and

"(cc) none of the conditions for denial of approval stated in paragraph (4) applies;

the approval shall be made effective on issuance by a United States district court of a decision and order that denies a preliminary injunction, or, in a case in which a preliminary injunction has been granted by a United States district court prohibiting the applicant from engaging in the commercial manufacture or sale of the drug, a decision and order that determines that the drug patent is invalid or that the drug patent is not otherwise infringed.

"(III) PROCEDURE.—In a civil action brought as described in subclause (II)—

"(aa) the civil action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business;

''(bb) each of the parties shall reasonably cooperate in expediting the civil action;

''(cc) the court shall not consider a motion for preliminary injunction unless the motion is filed within 90 days of commencement of the civil action; and

''(dd) the holder of the approved application or the owner of the patent shall be entitled to a preliminary injunction if the holder or owner demonstrates a likelihood of success on the merits and without regard to whether the holder or owner would suffer immediate or irreparable harm or to any other factor.'';

(2) by redesignating subparagraphs (C) and (D) as subparagraphs (F) and (G), respectively; and

(3) by inserting after subparagraph (B) the following:

''(C) EFFECTIVENESS ON CONDITION.—

''(i) NOTICE.—The applicant of an application that has been approved under subparagraph (A) but for which the approval has not yet been made effective under subparagraph (B) (referred to in this subparagraph as the 'previous application') and with respect to which a preliminary injunction has been issued prohibiting the commercial manufacture or sale of the drug subject to the previous application may submit to the Secretary a notice stating that—

''(I) the applicant expects to receive, within 180 days, a United States district court decision and order that vacates the preliminary injunction and denies a permanent injunction or determines that the patent is invalid or is otherwise not infringed (referred to in this subparagraph as a 'noninfringement decision');

''(II) requests the immediate issuance of an approval of the application conditioned on a noninfringement decision within the specified time;

"(III) agrees that—

"(aa) the applicant will not settle or otherwise compromise the noninfringement decision in any manner that would prevent or delay the immediate marketing of the drug under the approved application; and

"(bb) the applicant will notify the Secretary of the noninfringement decision (or if a decision is rendered that is not a noninfringement decision, will notify the Secretary of that decision) not later than 5 days after the date of entry of judgment; and

"(IV) consents to the immediate withdrawal of the approval, without opportunity for a hearing, if the applicant fails to comply with the agreement under subclause (III) or if the noninfringement decision is vacated by the district court or reversed on appeal.

''(ii) APPROVAL.—On receipt of a notice under clause (i), if none of the conditions for denial of approval stated in paragraph (4) applies, the Secretary shall immediately issue an effective approval of the application conditioned on the receipt of a noninfringement decision within the specified time, subject to immediate withdrawal if the applicant fails to comply with the agreement under clause (i)(III).

''(iii) EFFECT.—If a noninfringement decision is rendered, the date of the final decision of a court referred to in subparagraph (B)(iv)(II)(aa) shall be the date of the noninfringement decision, notwithstanding that the noninfringement decision may be, or has been, appealed.

''(D) CIVIL ACTION FOR DECLARATORY JUDGMENT.—A person that files an abbreviated application for a new drug under this section containing information showing that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a listed drug may bring a civil action—

''(i) against the holder of an approved application for the listed drug, for a declaratory judgment declaring that the certification made by the holder of the approved drug application under subsection (b)(5)(C) relating to the listed drug was not properly made; or

''(ii) against the owner of a patent that claims the listed drug, a method of using the listed drug, or the active ingredient in the listed drug, for a declaratory judgment declaring that the patent is invalid or will not otherwise be infringed by the new drug for which the applicant seeks approval.''.

(b) CONFORMING AMENDMENTS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking ''(j)(5)(D)(ii)'' each place it appears and inserting ''(j)(5)(G)(ii)'';

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(G)''; and

(3) in subsections (e) and (l), by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(G)''.

SEC. 203. ACCELERATED GENERIC DRUG COMPETITION.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 203) is amended—

(1) in subparagraph (B)(iv), by striking subclause (II) and inserting the following:

''(II) the earlier of—

''(aa) the date of a final decision of a court in an action described in clause (iii)(II) (from which no appeal has been or can be taken, other than a petition to the Supreme Court for a writ of certiorari) holding that the patent that is the subject of the certification is invalid or not otherwise infringed; or

''(bb) the date of a settlement order or consent decree signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certification is invalid or not otherwise infringed;''; and

(2) by inserting after subparagraph (D) the following:

"(E) FORFEITURE OF 180-DAY PERIOD.—

"(i) DEFINITIONS.—In this subparagraph:

"(I) FORFEITURE EVENT.—The term 'forfeiture event' means the occurrence of any of the following:

"(aa) FAILURE TO MARKET.—An applicant fails to market the drug by the later of—

"(AA) the date that is 60 days after the date on which the approval of the application for the drug is made effective under subparagraph (B)(iii) (unless the Secretary extends the date because of the existence of extraordinary or unusual circumstances); or

"(BB) if the approval has been made effective and a civil action has been brought against the appli-

cant for infringement of a patent subject to a certification under paragraph (2)(A)(vii)(IV) or a civil action has been brought by the applicant for a declaratory judgment that such a patent is invalid or not otherwise infringed, and if there is no other such civil action pending by or against the applicant, the date that is 60 days after the date of a final decision in the civil action, (unless the Secretary extends the date because of the existence of extraordinary or unusual circumstances).

''(bb) WITHDRAWAL OF APPLICATION.—An applicant withdraws an application.

''(cc) AMENDMENT OF CERTIFICATION.—An applicant, voluntarily or as a result of a settle-

ment or defeat in patent litigation, amends the certification from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III).

''(dd) FAILURE TO OBTAIN APPROVAL.—An applicant fails to obtain tentative approval of an application within 30 months after the date on which the application is filed, unless the failure is caused by—

''(AA) a change in the requirements for approval of the application imposed after the date on which the application is filed; or

''(BB) other extraordinary circumstances warranting an exception, as determined by the Secretary.

''(ee) FAILURE TO CHALLENGE PATENT.—In a case in which, after the date on which an

applicant submitted an application under this subsection, new patent information is submitted under subsection (c)(2) for the listed drug for a patent for which certification is required under paragraph (2)(A), the applicant fails to submit, not later than 60 days after the date on which the applicant receives notice from the Secretary under paragraph (7)(A)(iii) of the submission of the new patent information either a certification described in paragraph (2)(A)(vii)(IV) or a statement that the method of use patent does not claim a use for which the applicant is seeking approval under this subsection in accordance with paragraph (2)(A)(viii) (unless the Secretary extends the date because of extraordinary or unusual circumstances).

"(ff) MONOPOLIZATION.—The Secretary, after a fair and sufficient hearing, in consultation with the Federal Trade Commission, and based on standards used by the Federal Trade Commission in the enforcement of Acts enforced by the Federal Trade Commission, determines that the applicant at any time engaged in—

"(AA) anticompetitive or collusive conduct; or

"(BB) any other conduct intended to unlawfully monopolize the commercial manufacturing of the drug that is the subject of the application.

"(II) SUBSEQUENT APPLICANT.—The term 'subsequent applicant' means an applicant that submits a subsequent application under clause (ii).

"(ii) FORFEITURE EVENT OCCURS.—If—

"(I) a forfeiture event occurs;

"(II) no action described in subparagraph (B)(iii)(II) was brought against or by the previous applicant, or such an action was brought but did not result in a final judgment that included a finding that the patent is invalid; and

"(III) an action described in subparagraph (B)(iii)(II) is brought against or by the next applicant, and the action results in a final judgment that includes a finding that the patent is invalid;

the 180-day period under subparagraph (B)(iv) shall be forfeited by the applicant and shall become available to an applicant that submits a subsequent application containing a certification described in paragraph (2)(A)(vii)(IV).

"(iii) FORFEITURE EVENT DOES NOT OCCUR.—If a forfeiture event does not occur, the application submitted subse-

quent to the previous application shall be treated as the previous application under subparagraph (B)(iv).

''(iv) AVAILABILITY.—The 180-day period under subparagraph (B)(iv) shall be available only to—

''(I) the previous applicant submitting an application for a drug under this subsection containing a certification described in paragraph (2)(A)(vii)(IV) with respect to any patent; or

''(II) under clause (i), a subsequent applicant submitting an application for a drug under this subsection containing such a certification with respect to any patent;

without regard to whether an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.

''(v) APPLICABILITY.—The 180-day period described in subparagraph (B)(iv) shall apply only if—

"(I) the application contains a certification described in paragraph (2)(A)(vii)(IV); and

"(II)(aa) an action is brought for infringement of a patent that is the subject of the certification; or

"(bb) not later than 60 days after the date on which the notice provided under paragraph (2)(B)(ii) is received, the applicant brings an action against the holder of the approved application for the listed drug.".

(b) APPLICABILITY.—The amendment made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before June 7, 2002.

SEC. 204. NOTICE OF AGREEMENTS SETTLING CHALLENGES TO CERTIFICATIONS THAT A PATENT IS INVALID OR WILL NOT BE INFRINGED.

(a) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(kk) BRAND NAME DRUG COMPANY.—The term 'brand name drug company' means a person engaged in the manufacture or marketing of a drug approved under section 505(b).

''(ll) GENERIC DRUG APPLICANT.—The term 'generic drug applicant' means a person that has filed for approval or received approval of an abbreviated new drug application under section 505(j).''.

(b) NOTICE OF AGREEMENTS SETTLING CHALLENGES TO CERTIFICATIONS THAT A PATENT IS INVALID OR WILL NOT OTHERWISE BE INFRINGED.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(o) NOTICE OF AGREEMENTS SETTLING CHALLENGES TO CERTIFICATIONS THAT A PATENT IS INVALID OR WILL NOT OTHERWISE BE INFRINGED.—

''(1) IN GENERAL.—A brand name drug company and a generic drug applicant that enter into an agreement regarding the settlement of a challenge to a certification with respect to a patent on a drug

under subsection 505(b)(2)(A)(iv) shall submit to the Secretary and the Attorney General a notice that includes—

"(A) a copy of the agreement;

"(B) an explanation of the purpose and scope of the agreement; and

"(C) an explanation whether there is any possibility that the agreement could delay, restrain, limit, or otherwise interfere with the production, manufacture, or sale of the generic version of the drug.

"(2) FILING DEADLINES.—A notice required under paragraph (1) shall be submitted not later than 10 business days after the date on which the agreement described in paragraph (1) is entered into.

"(3) ENFORCEMENT.—

"(A) CIVIL PENALTY.—

"(i) IN GENERAL.—A person that fails to comply with paragraph (1) shall be liable for a civil penalty of not more than $20,000 for each day of failure to comply.

"(ii) PROCEDURE.—A civil penalty under clause (i) may be recovered in a civil action brought by the Secretary or the At-

torney General in accordance with section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)(1)).

''(B) COMPLIANCE AND EQUITABLE RELIEF.—If a person fails to comply with paragraph (1), on application of the Secretary or the Attorney General, a United States district court may order compliance and grant such other equitable relief as the court determines to be appropriate.

''(4) REGULATIONS.—The Secretary, with the concurrence of the Attorney General, may by regulation—

''(A) require that a notice required under paragraph (1) be submitted in such form and contain such documentary material and information relevant to the agreement as is appropriate to enable the Secretary and the Attorney General to determine whether the agreement may violate the antitrust laws; and

''(B) prescribe such other rules as are appropriate to carry out this subsection.''.

SEC. 205. PUBLICATION OF INFORMATION IN THE ORANGE BOOK.

(a) DEFINITION OF ORANGE BOOK.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) (as amended by section 205(a)) is amended by adding at the end the following:

''(mm) ORANGE BOOK.—The term 'Orange Book' means the publication published by the Secretary under section 505(b)(1).''.

(b) PUBLICATION OF INFORMATION IN THE ORANGE BOOK.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended—

(1) in the fourth sentence of paragraph (1), by inserting before the period at the end the following: ''in a publication entitled 'Approved Drug Products With Therapeutic Equivalence Indications' (commonly known as the 'Orange Book')''; and

(2) by adding at the end the following:

''(5) PUBLICATION OF INFORMATION IN THE ORANGE BOOK.—

''(A) DEFINITIONS.—In this paragraph:

''(i) INTERESTED PERSON.—The term 'interested person' includes—

''(I) an applicant under paragraph (1);

''(II) any person that is considering engaging in the manufacture, production, or marketing of a drug with respect to which there may be a question whether the drug infringes the patent to which information submitted under the second sentence of paragraph (1) pertains;

''(III) the Federal Trade Commission; and

''(IV) a representative of consumers.

''(ii) QUALIFIED PATENT INFORMATION.—The term 'qualified patent information' means information that meets the requirement of the second sentence of paragraph (1) that a patent with respect to which information is submitted under that sentence be a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug that is the subject of an application under paragraph (1).

"(B) DUTY OF THE SECRETARY.—The Secretary shall publish in the Orange Book only information that is qualified patent information.

"(C) CERTIFICATION.—

"(i) IN GENERAL.—Information submitted under the second sentence of paragraph (1) shall not be published in the Orange Book unless the applicant files a certification, subject to section 1001 of title 18, United States Code, and sworn in accordance with section 1746 of title 28, United States Code, that discloses the patent data or information that forms the basis of the entry.

"(ii) CONTENTS.—A certification under clause (i) shall—

"(I)(aa) identify all relevant claims in the patent information for which publication in the Orange Book is sought; and

"(bb) with respect to each such claim, a statement whether the claim covers an approved drug, an approved method of using the approved drug, or the active ingredient in the approved

drug (in the same physical form as the active ingredient is present in the approved drug);

''(II) state the approval date for the drug;

''(III) state an objectively reasonable basis on which a person could conclude that each relevant claim of the patent covers an approved drug, an approved method of using the approved drug, or the active ingredient in the approved drug (in the same physical form as the active ingredients is present in the approved drug);

''(IV) state that the information submitted conforms with law; and

''(V) state that the submission is not made for the purpose of delay or for any improper purpose.

''(iii) REGULATIONS.—

''(I) IN GENERAL.—Not later than 16 months after the date of enactment of this paragraph, the Secretary, in consultation with the United States Patent and Trademark Office,

shall promulgate regulations governing certifications under clause (i).

''(II) CIVIL PENALTIES.—The regulations under subclause (I) shall prescribe civil penalties for the making of a fraudulent or misleading statement in a certification under clause (i).

''(D) CONSULTATION.—For the purpose of deciding whether information should be published in Orange Book, the Secretary may consult with the United States Patent and Trademark Office.

''(E) PUBLICATION OF DETERMINATION.—The Secretary shall publish in the Federal Register notice of a determination by the Secretary whether information submitted by an applicant under the second sentence of paragraph (1) is or is not qualified patent information.

''(F) PETITION TO RECONSIDER DETERMINATION.—

''(i) IN GENERAL.—An interested person may file with the Secretary a petition to reconsider the determination.

''(ii) CONTENTS.—A petition under clause (i) shall describe in detail all evidence and present all reasons relied on by the petitioner in support of the petition.

''(iii) NOTICE.—The Secretary shall publish in the Federal Register notice of the filing of a petition under clause (i).

''(iv) RESPONSE.—Not later than 30 days after publication of a notice under clause (iii), any interested person may file with the Secretary a response to the petition.

''(v) REPLY.—Not later than 15 days after the filing of a response under clause (iv), the petitioner may file with the Secretary a reply to the response.

''(vi) REGULATIONS.—The Secretary may promulgate regulations providing for any additional procedures for the conduct of challenges under this subparagraph.''.

(c) EXPEDITED REVIEW OF THE ORANGE BOOK.—

(1) USE OF DEFINED TERMS.—Terms used in this subsection that are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.) (as

amended by this section) having the meanings given the terms in that Act.

(2) EXPEDITED REVIEW.—As soon as practicable after the date of enactment of this Act, the Secretary shall—

(A) complete a review of the Orange Book to identify any information in the Orange Book that is not qualified patent information; and

(B) delete any such information from the Orange Book.

(3) PRIORITY.—In conducting the review under paragraph (2), the Secretary shall give priority to making determinations concerning information in the Orange Book with respect to which any interested person may file a petition for reconsideration under paragraph (5)(F) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), as added by subsection (b).

(d) DIFFERENCES IN LABELING.—Section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is amended—

(1) in subparagraph (A)(v)—

(A) by striking ''subparagraph (C) or because'' and inserting ''subparagraph (C), because''; and

(B) by inserting after ''manufacturers'' the following: '', or because of the omission of an indication or other aspect of labeling that is required by patent protection or exclusivity accorded under paragraph (5)(D)''; and

(2) by adding at the end the following:

''(D) LABELING CONSISTENT WITH LABELING FOR EARLIER VERSION OF LISTED DRUG.—For the purposes of subparagraph (A)(v), information showing that labeling proposed for the new drug that is the same as the labeling previously approved for the listed drug, although not for the current version of the listed drug, shall be deemed to be the same labeling as that approved for the listed drug so long as the previously approved labeling is not incompatible with a safe and effective new drug.''.

SEC. 206. NO ADDITIONAL 30-MONTH EXTENSION.

Section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (j)(5)(B)(iii) is amended by inserting after the fourth sentence the following: ''Once a thirty-month period begins under the second sentence of this clause with respect to any application under this subsection, there shall be no additional thirty-month period or extension of the thirty-month period with respect

to the application by reason of the making of any additional certification described in subclause (IV) of paragraph (2)(A)(vii) or for any other reason.''.

TITLE III—EXPANSION OF ACCESS THROUGH EXISTING PROGRAMS

SEC. 301. MEDICARE COVERAGE OF ALL ANTICANCER ORAL DRUGS.

(a) IN GENERAL.—Section 1861(s)(2)(Q) of the Social Security Act (42 U.S.C. 1395x(s)(2)(Q)) is amended by striking ''anticancer chemotherapeutic agent for a given indication,'' and all that follows and inserting ''anticancer agent for a medically accepted indication (as defined in subsection (t)(2)(B));''.

(b) CONFORMING AMENDMENT.—Section 1834(j)(5)(F)(iv) of the Social Security Act (42 U.S.C. 1395m(j)(5)(F)(iv)) is amended by striking ''therapeutic''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to drugs furnished on or after the date that is 90 days after the date of enactment of this Act.

SEC. 302. REMOVAL OF STATE RESTRICTIONS.

(a) THERAPEUTIC EQUIVALENCE.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (5)(A)—

(A) by striking ''(5)(A) Within one hundred and eighty days of the'' and inserting the following:

''(5) TIME PERIODS.—

''(A) APPROVAL OR DISAPPROVAL.—

''(i) IN GENERAL.—Not later than 180 days after the date of''; and

(B) by adding at the end the following:

''(ii) FINDING REGARDING THERAPEUTIC EQUIVALENCE.—When the Secretary approves an application submitted under paragraph (1), the Secretary shall include in the approval a finding whether the drug for which the application is approved (referred to in this paragraph as the 'subject drug') is the therapeutic equivalent of a listed drug.

''(iii) THERAPEUTIC EQUIVALENCE.—For purposes of clause (ii), a subject drug is the therapeutic equivalent of a listed drug if—

''(I) all active ingredients of the subject drug, the dosage form of the subject drug, the route of administra-

tion of the subject drug, and the strength or concentration of the subject drug are the same as those of the listed drug and the compendial or other applicable standard met by the subject drug is the same as that met by the listed drug (even though the subject drug may differ in shape, scoring, configuration, packaging, excipients, expiration time, or (within the limits established by paragraph (2)(A)(v)) labeling);

''(II) the subject drug is expected to have the same clinical effect and safety profile as the listed drug when the subject drug is administered to patients under conditions specified in the labeling; and

''(III) the subject drug—

''(aa)(AA) does not present a known or potential bioequivalence problem; and

''(BB) meets an acceptable in vitro standard; or

''(bb) if the subject drug presents a known or potential bioequivalence problem, is shown to meet an appropriate bioequivalence standard.

''(iv) FINDING.—If Secretary finds that the subject drug meets the requirements of clause (iii) with respect to a listed drug, the Secretary shall include in the approval of the application for the subject drug a finding that the subject drug is the therapeutic equivalent of the listed drug.''; and

(2) in paragraph (7)(A)(i)(II), by striking ''and the number of the application which was approved'' and inserting '', the number of the application that was approved, and a statement whether a finding of therapeutic equivalence was made under paragraph (5)(A)(iv), and if so the name of the listed drug to which the drug is a therapeutic bioequivalent''.

(b) STATE LAWS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(10) STATE LAWS.—No State or political subdivision of a State may establish or continue in ef-

fect with respect to a drug that is the subject of an application under paragraph (5) any requirement that is different from, or in addition to, any requirement relating to therapeutic equivalence applicable to the drug under paragraph (5).''.

SEC. 303. MEDICAID DRUG USE REVIEW PROGRAM.

(a) IN GENERAL.—Section 1927(g)(2) of the Social Security Act (42 U.S.C. 1396r–8(g)(2)) is amended by adding at the end the following:

''(E) GENERIC DRUG SAMPLES.—The program shall provide for the distribution of generic drug samples of covered outpatient drugs to physicians and other prescribers.''.

(b) FEDERAL PERCENTAGE OF EXPENDITURES.—Section 1903(a)(3)(D) of the Social Security Act (42 U.S.C. 1396b(a)(3)(D)) is amended by striking ''in 1991, 1992, or 1993,'' and inserting ''(beginning with fiscal year 2003)''.

(c) EFFECTIVE DATE.—The amendments made by this section take effect on October 1, 2002.

SEC. 304. CLARIFICATION OF INCLUSION OF INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS IN THE BEST PRICE EXEMPTIONS ESTABLISHED FOR PURPOSES OF THE MEDICAID DRUG REBATE PROGRAM.

Section 1927(c)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)) is amended—

(1) in subclause (II), by striking ''and'' at the end;

(2) in subclause (III), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(IV) with respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, shall, in addition to any prices excluded under clause (i)(I), exclude any price charged on or after the date of enactment of this subparagraph, for any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, inpatient hospital services (and for which payment may be made under this title as part of payment for and

not as direct reimbursement for the drug).''.

SEC. 305. UPPER PAYMENT LIMITS FOR GENERIC DRUGS UNDER MEDICAID.

Section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)) is amended by striking paragraph (4) and inserting the following:

''(4) ESTABLISHMENT OF UPPER PAYMENT LIMITS.—

''(A) IN GENERAL.—The Administrator of the Centers for Medicare & Medicaid Services shall establish a upper payment limit for each multiple source drug for which the FDA has rated 3 or more products therapeutically and pharmaceutically equivalent.

''(B) PUBLIC AVAILABILITY OF NATIONAL DRUG CODE.—The Administrator of the Centers for Medicare & Medicaid Services shall make publicly available, at such time and together with the publication of the upper payment limits established in accordance with subparagraph (A), the national drug code (commonly referred to as the 'NDC') for each drug used as the reference product to establish the

upper payment limit for a particular multiple source drug.

''(C) DEFINITION OF REFERENCE PRODUCT.—In subparagraph (B), the term 'reference product' means the specific drug product, the price of which is used by the Administrator of the Centers for Medicare & Medicaid Services to calculate the upper payment limit for a particular multiple source drug.''.

TITLE IV—GENERAL PROVISIONS

SEC. 401. REPORT.

(a) IN GENERAL.—Not later than the date that is 5 years after the date of enactment of this Act, the Federal Trade Commission shall submit to Congress a report describing the extent to which implementation of the amendments made by this Act—

(1) has enabled products to come to market in a fair and expeditious manner, consistent with the rights of patent owners under intellectual property law; and

(2) has promoted lower prices of drugs and greater access to drugs through price competition.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $1,000,000.

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